Applicant: Tetsuji Yamaoka et al. Attorney's Docket No.: 18900-0004US1 / 200640/US

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REMARKS

In response to the Office action dated March 3, 2011, Applicants have incorporated the limitations recited in claims 4-6 into claim 1, cancelled claims 2-6, and amended claims 7, 10, and 11. Applicants have also limited R₉ recited in claim 1 to a saturated or unsaturated aliphatic or alicyclic hydrocarbon group having 5 to 30 carbon atoms. Support for the amendment to R₉ can be found, *e.g.*, at page 12, lines 12-15 of the specification. No new matter has been introduced by the above amendments. Claims 1 and 7-11 are presented for examination.

Claims 1-11 were rejected under 35 U.S.C. §103(a) as obvious from Kurisawa et al., *J. Control Release*, 2000, 68:1-8 ("Kurisawa") in view of Fajac et al., *Glycoconjugate Journal*, 2001, 18:723-729 ("Fajac") and Aoyagi et al., *J. Biomater. Sci. Polymer Edn.*, 2000, 11:101-110 ("Aoyagi").

Independent claim 1 is discussed first. Claim 1, as amended, recites a copolymer having a repeating unit (A) represented by formula (IV), a repeating unit (B) represented by formula (III), and a repeating unit (C) represented by formula (V).

Kurisawa discloses a terpolymer gene carrier, i.e., poly(N-isopropylacrylamide-co-2-(dimethylamino)ethyl methacrylate-co-butylmethacrylate). *See, e.g.*, the abstract. The Office asserts that

"Kurisawa et al. do not teach a saccharified copolymer (claims 1 and 11). However, using a saccharified copolymer is suggested by the prior art. For example, Fajac et al., teach cell-specific DNA delivery by using glycosylated carriers capable of binding lectins expressed by the cell of interest (Abstract; p. 724, column 1). It would have been obvious to one of skill in the art, at the time the invention was made, to glycosylate the carrier of Kurisawa et al. by using N-isopropylacrylamide derivatized with sugars, with a reasonable expectation of success. ... One of skill in the art would have reasonably expected to be successful in doing so because the prior art teaches that reactive groups can be successfully introduced into N-isopropylacrylamide (see Aoyagi et al. Abstract)."

See the Office action, the paragraph bridging pages 3 and 4; emphasis added. Applicants respectfully disagree.

Aoyagi discloses introducing reactive groups into <u>polymeric chains</u> of poly(N-isopropylacrylamide) (PIPAAm) by <u>copolymerizing</u> IPAAm with another monomer, such as 2-carboxyisopropylacrylamide (CIPAAm). *See, e.g.*, the abstract. Contrary to the Examiner's

¹ Applicants have cancelled claims 2-6. Thus, the rejection of these claims is now moot.

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assertion, Aoyagi does not disclose or render obvious modifying the monomer Nisopropylacrylamide with a sugar residue.

Fajac discloses glycosylated <u>polylysine</u> and glycosylated <u>polyethyleneimine</u> as gene therapy of cystic fibrosis. *See, e.g.*, the abstract. Like Aoyagi, Fajac also does not disclose or render obvious modifying N-isopropylacrylamide with a sugar residue.

Thus, one skilled in the art, in view of Aoyagi and Fajac, would not have been motivated to modify the N-isopropylacrylamide monomer in the terpolymer disclosed in Kurisawa to provide the polymer recited in claim 1.

Even if the three cited references were somehow combined, the result would still not have been the polymer recited in claim 1.

First, Fajac is the only cited reference that discloses a glycosylated polymer. However, the glycosylated polymers disclosed in Fajac, i.e., glycosylated polylysine and polyethyleneimine, have a polymer chain structure significantly different from that of the sugar-containing repeating unit (B), which has a vinyl ester polymer chain structure (i.e., -CH(OR)-CH₂-; see formula (III) recited in claim 1). Thus, incorporating the glycosylated polylysine or polyethyleneimine disclosed in Fajac into the polymer disclosed in Kurisawa would not result in or render obvious the polymer recited in claim 1.

Second, even if the repeating unit N-isopropylacrylamide disclosed in Kurisawa were somehow modified to include a sugar residue (which Applicants do not concede), the result would have been a repeating unit containing an <u>acrylamide</u> polymer chain structure (i.e., -CH(C(O)R)-CH₂-), not the sugar-containing repeating unit (B) recited in claim 1, which has a <u>vinyl ester</u> polymer chain structure (i.e., -CH(OR)-CH₂-).

Finally, the repeating unit (C) recited in claim 1 has been limited to a group in which R₉ is a saturated or unsaturated aliphatic or alicyclic hydrocarbon group having <u>5 to 30 carbon</u> atoms. By contrast, in the terpolymer disclosed in Kurisawa, the corresponding repeating unit, i.e., butylmethacrylate, contains a butyl group (i.e., a saturated aliphatic hydrocarbon group having <u>four</u> carbon atoms) that corresponds to R₉. In other words, Kurisawa does not disclose or render obvious a polymer containing the repeating unit (C) recited in claim 1. Further, neither Aoyagi nor Fajac discloses or renders obvious a polymer containing the repeating unit (C)

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recited in claim 1, in which R₉ is a saturated or unsaturated aliphatic or alicyclic hydrocarbon group having 5 to 30 carbon atoms.

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In sum, a combination of Kurisawa, Fajac, and Aoyagi would not have resulted in or render obvious the polymer recited in claim 1.

For at least the reasons set forth above, claim 1 would not have been obvious from Kurisawa, Fajac, and Aoyagi. Since claims 7-11 depend from claim 1, they also would not have been obvious from these references.

Applicants submit that all pending claims are now in condition for allowance, an action of which is requested.

Any circumstance in which Applicants have: (a) addressed certain comments of the Examiner does not mean that Applicants concede other comments of the Examiner; (b) made arguments for the patentability of some claims does not mean that there are no other good reasons for the patentability of those claims and other claims; or (c) amended or canceled a claim does not mean that Applicants concede any of the Examiner's positions with respect to that claim or other claims.

Please apply any charges to deposit account 06-1050, referencing Attorney's Docket No. 18900-0004US1.

Respectfully submitted,

Date: May 26, 2011

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